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B. Braun Avitum AG Special 510(k) Premarket Notification Diacap Polysulfone HiFlo 23 Hemodialyzer

5. 510(k) SUMMARY

APR 2 2 2010

APPLICANT:

B. Braun Avitum AG

Schwarzenberger Weg 73-79 34212 Melsungen, Germany

Establishment Registration Number: 3002879653

SUBMITTER:

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610-266-0500

CONTACT:

Angela J. Caravella

Sr. Regulatory Affairs Analyst

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DEVICE NAME:

Diacap® Polysulfone HiFlo 23 Hemodialyzer

COMMON OR

USUAL NAME:

High Permeability Hemodialysis System

DEVICE

Class II per 21 CFR § 876.5860

CLASSIFICATION:

Product Code KDI

CURRENTLY MARKETED

DEVICE (PREDICATE):

Diacap® LO PS (10, 12, 15) and Diacap® HI PS (10, 12, 15,

18, 20) Hemodialyzers, (K071518)

DESCRIPTION:

The Diacap® Polysulfone HiFlo 23 Hemodialyzer is a high permeability dialyzer intended to be used in acute and chronic hemodialysis. It is composed of polysulfone hollow fiber capillary membranes in a polycarbonate housing with a polyurethane potting resin and a silicone O-ring. The proposed Diacap HiFlo 23 hemodialyzer will be available in one model, the 23, which represents the effective surface area of 2.3m². The dialyzer is intended for single use and is

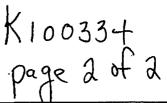
provided sterile.

INTENDED USE:

The Diacap® Polysulfone HiFlo 23 Hemodialyzer is designed

for single use in acute and chronic hemodialysis.

B. Braun Avitum AG Special S10(k) Premarket Notification Diacap Polysulfone HiFlo 23 Hemodialyzer



SUBSTANTIAL EQUIVALENCE:

Diacap[®] Polysulfone HiFlo 23 Hemodialyzer has the same intended use and utilizes the same fundamental technology as the predicate device, the currently marketed Diacap LO PS (10, 12, 15) and Diacap HI PS (10, 12, 15, 18, 20) Hemodialyzers, (K071518). The Diacap HiFlo 23 Hemodialyzer is a modified version of the existing Diacap LO PS and HI PS dialyzers and can be considered an extension to the line of B. Braun Polysulfone Dialyzers.

The technological characteristics of the Diacap Polysulfone HiFlo 23 Hemodialyzer are equivalent to those of the existing Diacap polysulfone dialyzers. The Diacap Polysulfone HiFlo 23 Hemodialyzer is similar to the predicate device in material composition. Changes in the design of the proposed dialyzer include an increased surface area and two alternate materials have been added: polyurethane (PUR) potting resin and an alternate silicone material qualified for the dialyzer O-ring.

These changes do not pose a significant impact upon the fundamental technology of the Diacap polysulfone capillary dialyzers, as identified within the Risk Analysis. Verification and validation testing for the proposed dialyzer have been completed and all acceptance criteria have been met. The testing demonstrated that there are no differences between the predicate and the proposed device that raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration 10903 New Hampshire Avenue Document Mail Center - WO66-G609 Silver Spring, MD 20993-0002

JUN - 3 2010

B.Braun Avitum AG
Ms. Angela J. Caravella
Sr. Regulatory Affairs Analyst
B. Braun Medical, Inc.
901 Marcon Boulevard
ALLENTOWN PA 18109-9341

Re: K100334

Diacap[®] Polysulfone HiFlo 23 Hemodialyzer Regulation Number: 21 CFR §876.5860

Regulation Name: High permeability hemodialysis system

Regulatory Class: II Product Code: KDI Dated: March 30, 2010 Received: April 1, 2010

Dear Ms. Caravella:

This letter corrects our substantially equivalent letter of April 22, 2010. We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth

in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris

Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure